UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,327	03/12/2007	Nariyoshi Shinomiya	VAN67 P-328A	7013

277 7590 09/17/2008

PRICE HENEVELD COOPER DEWITT & LITTON, LLP
695 KENMOOR, S.E.
P O BOX 2567
GRAND RAPIDS, MI 49501

EXAMINER	
WOLLENBERGER, LOUIS V	

ART UNIT	PAPER NUMBER
1635	

MAIL DATE	DELIVERY MODE
09/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/599,327	SHINOMIYA ET AL.	
	Examiner	Art Unit	
	Louis Wollenberger	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20 and 38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20 and 38* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Notice to comply*.

DETAILED ACTION

Preliminary Amendment

Applicant's preliminary amendment to the claims, filed 9/26/06, is acknowledged. With entry of the amendment, claims 1-20 and 38 are pending and subject to restriction as follows.

Notice to Comply/Sequence Rules

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

In the instant case, the application does not contain, as a separate part of the disclosure, a paper or compact disc copy, or sequence listing disclosing each nucleotide and/or amino acid sequence, as required by 37 CFR 1.821(c). Each sequence disclosed must appear separately in the "Sequence Listing."

Accordingly, Applicant must furnish a sequence listing in compliance with 37 CFR 1.821-1.825 before examination can begin.

Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g).

Claim Objections

Claim 1 is objected to because of an apparent inconsistency with the disclosure in the specification. Claim 1 recites the mRNA encoded by murine c-*met* (SEQ ID NO:2). However, page 12 of the specification teaches that SEQ ID NO:2 corresponds to the human Met protein, not murine c-met DNA. Rather, it would appear that the murine c-met gene is SEQ ID NO:3. See page 12. Clarification and/or correction is requested.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-20 and 38, drawn to an interfering RNA molecule having a sequence that is sufficiently complementary to a sequence of mRNA encoded by **human *c-met* (SEQ ID NO:1),** and to RNAi molecules, expression constructs, and vectors thereof, and to a method of use thereof for treating a *c-met* tumor or cancer in a subject. Election of this group requires the further election of a single RNAi molecule from claims 4, 5, 6, and 7; a single type of expression vector (transient or stable) from claims 15 and 16; and a single type of Ad5 viral vector from claims 19 and 20.

Group II, claim(s) 1-20 and 38, drawn to an interfering RNA molecule having a sequence that is sufficiently complementary to a sequence of mRNA encoded by **murine *c-met* (SEQ ID NO:2),** and to RNAi molecules, expression constructs, and vectors thereof, and to a method of use thereof for treating a *c-met* tumor or cancer in a subject. Election of this group requires the further election of a single RNAi molecule from claims 4, 5, 6, and 7; a single type of expression vector (transient or stable) from claims 15 and 16; and a single type of Ad5 viral vector from claims 19 and 20.

Group I, claim(s) 1-20 and 38, drawn to an interfering RNA molecule having a sequence that is sufficiently complementary to a sequence of mRNA encoded by ***c-met of any non-human and non-murine* mammal,** and to RNAi molecules, expression constructs, and vectors thereof, and to a method of use thereof for treating a *c-met* tumor or cancer in a subject. Election of this group requires the further election of a single RNAi molecule from claims 4, 5, 6, and 7; a single type of expression vector (transient or stable) from claims 15 and 16; and a single type of Ad5 viral vector from claims 19 and 20.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature of Group I is an interfering RNA molecule complementary to a human *c-met*, which is not specifically required by or present in Group II or III. Similarly, the special technical features of Groups II and III are

RNAi molecules complementary to murine *c-met* or *c-met* of any other mammal, respectively. Accordingly, Groups I-III lack unity of invention *a priori* (MPEP 1850.II).

Further elections

Groups I, II, and III comprise claims to a plurality of different inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1 and 13.2. The different inventions are distinguished by:

1. the sequence (i.e., SEQ ID NO) of the RNAi molecule used to inhibit *c-met* (claims 4-7);
2. the type of vector used for delivering the RNAi molecule (claims 15 and 16); and
3. the physical and/or chemical characteristics of the Ad5 vector encoding the RNAi molecule (claims 19 and 20).

As evidenced by their mutually exclusive structural/functional characteristics, the alternative RNAi molecules and vectors represent different special technical features. For example, as shown in Table 2, page 25, of the specification, the siRNA comprising SEQ ID NO:9 is structurally distinct from the siRNA comprising SEQ ID NO:10, or 11 through 18. Thus, each molecularly distinct siRNA represents a special technical feature of the method in which it is used. Similar reasoning applies to each of the alternatives recited in categories 2 and 3 above.

Accordingly, the alternative interfering RNAs and vectors and methods of use thereof of categories 1-3 lack unity invention *a priori*. Applicant is required to elect one alternative from each category, 1-3, for prosecution on the merits with the elected group. Applicant is advised that

the election from category 2 must be consistent with the election from category 3, and vice versa. Similarly, the election from category 3 must be consistent with the RNAi molecule elected from category 1, and vice versa.

Applicant is further encouraged to ensure the elected RNAi molecule is one complementary to the c-met target to which the elected Group is drawn.

Linked inventions

To the extent it is limited to one particular mRNA target, Claim 1 link(s) the RNAi molecules (i.e., inventions) of claims 4-7 that are specifically complementary to that target. The restriction requirement among the linked inventions is **subject to** the nonallowance of the linking claim(s). Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the

provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Conclusion

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis Wollenberger whose telephone number is (571)272-8144. The examiner can normally be reached on M-F, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571)272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Louis Wollenberger/
Examiner, Art Unit 1635
September 10, 2008

Notice to Comply	Application No.	Applicant(s)	
	10599327	SHINOMIYA ET AL.	
	Examiner	Art Unit	
	Louis Wollenberger	1635	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set in the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☒ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☐ 7. Other:

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the specification**.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (571) 272-2510
For CRF Submission Help, call (571) 272-2501/2583.
PatentIn Software Program Support
Technical Assistance.....703-287-0200
To Purchase PatentIn Software.....703-306-2600

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR REPLY

Sequence Count Sheet	Application/Control No.	Applicant(s)	
	10/599,327	SHINOMIYA ET AL.	
	Examiner	Art Unit	
	Louis Wollenberger	1635	

DATE OF COUNT

Mark only one space below

☐ **(CRFN)** (CRF is unreadable; use CRF Diskette Problem Report)

☐ **(CRFD)** (CRF does not comply; use Notice to Comply)

☒ **(CRFR)** (CRF required but none submitted; use Notice to Comply)

☐ **(bona fide)** (second or subsequent letter to applicant reporting bona fide attempt to comply; use Notice to Comply and send copy of RSL)

☐ **(non bona fide)** (second or subsequent letter to applicant reporting non-bona fide attempt to comply; use Notice to Comply and send copy of RSL)